

PRODUCT INGREDIENT SOURCE INFORMATION IS NOT INCLUDED

DATE OUT: 02/OCT/2001

SUBJECT: PRODUCT CHEMISTRY REVIEW OF: Manufacturing-Use [] End-Use Product [X]
DP BARCODE #: D277191 EPA RECEIVED DATE: 13/AUG/2001 FILE SYMBOL/REG # 9404-IT
PRODUCT NAME: Permethrin 0.25% Insecticide Granules, 0.25% permethrin MRIDs.: 454773-01
COMPANY NAME: Sunniland Corporation ACTION CODE: 161

FROM: Sami Malak, Chemist *Sami Malak*
Technical Review Branch/RD (7505C)

TO: 03 Arnold Layne/Linda Gerber
Insecticide Branch/RD (7505C)

INTRODUCTION:

In a letter dated 08/AUG/2001, H. R. McLane, Inc. of Miami, Florida on behalf of the applicant, Sunniland Corporation, responded to EPA's letter of 02/AUG/2001 reflecting a product chemistry memorandum (DP #275563, L. Kutney, 25/JUL/2001) and submitted product chemistry data. The applicant requested a FIFRA sec.3(c)(3)(B)(i)(I) "me-too" registration of subject product claiming its similarity to Permethrin 0.25% Granules, Reg. No. 51036-322. In addition to the submitted product chemistry data, the applicant included a proposed basic formulation, CSF dated 08/AUG/2001, and product's label EPA received 13/AUG/2001.

FINDINGS:

- 1a. The subject product, an insecticide, is intended for insect control in residential lawns, golf courses, and ornamental recreational turf.
- 1b. The subject product is produced by a non-integrated formulation system, meaning that the [REDACTED] is registered. The product contains 0.25% permethrin, [REDACTED]
2. The subject product is substantially similar to permethrin 0.25% granules, Reg. No. 51036-322. Both products contain [REDACTED] the same nominal concentration, same upper/lower limits, and physical/chemical properties.
3. The submitted/referenced product chemistry data is adequate and support a FIFRA sec.3(c)(3)(B)(i)(I) "me-too" registration of subject product.
4. Adequate analytical method is available for enforcement. The method was previously submitted and reviewed in connection with the registration of [REDACTED]
[REDACTED]
5. The label claim nominal concentrations of 0.25% permethrin is consistent with that on the CSF both are in compliance with the regulations of PR Notice 91-2. Further, the storage and disposal statement and the physical or chemical hazards statement are in compliance with the regulations of 40CFR§156.10.
6. The submitted product's basic formulation, CSF dated 08/AUG/2001, was filled out correctly and completely and agree with the label claim nominal concentration as per the regulations of PR Notice 91-2. Further, the upper and lower certified limits are within the standard limits of 40CFR§158.175(b)(2). All ingredients claimed on the CSF are cleared for use in pesticide formulations.

CONCLUSIONS:

1. From the product chemistry view point, the subject product is substantially similar to permethrin 0.25% granules, Reg. No. 51036-322.
2. The applicant has satisfied product chemistry data requirements for a FIFRA sec.3(c)(3)(B)(i)(I) "me-too" registration of subject product. Product's label and CSF are acceptable as per Findings 5 & 6 above.

REVIEW OF PRODUCT CHEMISTRY DATA:

1. A statement of data confidentiality dated 08/AUG/2001 was included with this submission claiming no confidentiality of any of the submitted data on the basis of its falling within the scope of FIFRA§10(d)(1)(A), (B), or (C).
2. A GLP statement was included with the data indicating that the submitted studies were conducted in compliance with the GLP requirements of 40CFR§160.

DATA SUBMITTED

MRID #454773-01: The submitted studies entitled: "Permethrin 0.25% Insecticide Granules, Product Chemistry Data Requirements of 40CFR§158.165 & 167, Guidelines Reference Numbers #61-2 & 61-3." The studies were authored by H. R. McLane, Inc. for Sunniland Corporation; Completed on 18/AUG/2001 (5 pages).

Group A, Series 830-Product Identity, Composition, and Analysis (40 CFR 155, 160, 162, 167, 175 & 180)

830-1550 Product Identity and Composition

The subject product contains one registered [REDACTED] of active ingredient plus cleared inert ingredients (refer to product's Csf dated 08/AUG/2001).

830-1600 Description of Materials Used to Produce the Product:
Refer to Confidential appendix A.

830-1650 Description of Formulation Process:
Refer to Confidential appendix A.

830-1670 Discussion of Formation of Impurities:
Refer to Confidential appendix A.

830-1700 Preliminary Analysis:
Refer to Confidential appendix A.


830-1750 Certified Limits:
Refer to Confidential appendix A.

830-1800 Enforcement Analytical Method:

Adequate analytical method is available for enforcement. The method was previously submitted and reviewed in connection with the registration of [REDACTED] permethrin 0.25% granules,

Reg. No. 51036-322.

Group B, Series 830-Physical and Chemical Properties (40 CFR 158.190):

GUIDELINE REFERENCE NO.(GRN 830.)/TITLE	VALUE OR QUALITATIVE DESCRIPTION
.6302 Color	 brown/buff/tan..
.6303 Physical State	Free Flowing Granules.
.6304 Odor	Earth-type little odor.
.6314 Oxidation/Reduction: Incompatibility	Not considered to be strong oxidizing or reducing agents.
.6315 Flammability/Flame Extension	NA
.6316 Explodability	NA. None of the ingredients in the product is high energy chemical.
.6317 Storage Stability	Stable for a period of one year.
.6319 Miscibility	NA.
.6320 Corrosion Characteristics	Non considered to be corrosive.
.6321 Dielectric Breakdown Voltage	NA. Granule product for soil treatment.
.7000 pH	NA
.7100 Viscosity	NA
.7300 Density/Relative Density Bulk Density	29-32 lb/ft ³

Confidential Appendix A

830-1600 Description of Materials Used to Produce the Product:

One registered [REDACTED] of active ingredient [REDACTED] cleared inert ingredients (refer to product's CSF dated 08/AUG/2001).

830-1650 Description of Formulation Process:

[REDACTED]

830-1670 Discussion of Formation of Impurities:

The applicant reported no impurities $\geq 0.1\%$ by weight. There was no chemical reaction during or after formulation.

830-1700 Preliminary Analysis:

Not required for subject product.

830-1750 Certified Limits:

The applicant reported the same limits as those in product's CSF dated 08/AUG/2001.

INERT INGREDIENT INFORMATION IS NOT INCLUDED

MANUFACTURING PROCESS INFORMATION IS NOT INCLUDED